



Endoscopy

SECTION 5
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

SEP 15 2006

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4347
Fax: 508-683-5939

Contact: Elena Bickoff
Regulatory Affairs Specialist
Date Prepared: June 30, 2006

2. Device:

Trade Name: Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System
Common Name: Expandable, metallic colonic stent
Classification Name: Stent, colonic, metallic, expandable
Regulation Number: 878.3610
Product Code: MQR
Classification: Class II

3. Predicate Device(s):

- Boston Scientific Corporation's Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System, K042065
- Boston Scientific Corporation's Ultraflex™ Precision™ Colonic Stent System, K060323
- Boston Scientific Corporation's Wallstent® Enteral Prosthesis, K000281

All above predicates are class II devices per 21 CFR 878.3610

4. Device Description:

The proposed Wallflex Enteral Stent with Anchor Lock Delivery System consists of 2 components: an implantable metal stent and a delivery system. The proposed stent is manufactured of Nitinol and offered in two diameters, a 25mm body with a 30mm flare, and a 22mm body with a 27mm flare. Each diameter is offered in three lengths, 6cm, 9cm, and 12cm. The proposed Anchor Lock delivery system consists of a coaxial tubing assembly that constrains the stent on the delivery catheter shaft until the stent is released by retracting the exterior tube.

Premarket Notification, Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System

000010

5. Intended Use:

The Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

6. Technological Characteristics:

The proposed Wallflex Enteral Colonic Stent with Anchor Lock Delivery System has the identical technological characteristics as the currently marketed Wallflex Enteral Colonic Stent with Anchor Lock Delivery System (K042065).

7. Performance Data:

As this is a request for an expanded indication and introduces no new materials or design changes the performance testing presented in K042065 was not repeated.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Wallflex Enteral Colonic stent is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex™ Precision™ Colonic stent and Wallstent® Enteral stent. The proposed delivery system is substantially equivalent to the Wallflex Anchor Lock delivery system.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 15 2006

Ms. Elena Bickoff
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K061877

Trade/Device Name: Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System
Model numbers M00565040, -5050, -5060, -5070, -5080, -5090,
-5100, -5110, -5120, -5130, -5140 and -5150

Regulation Number: 21 CFR §878.3610

Regulation Name: Esophageal prosthesis

Regulatory Class: II

Product Code: MQR

Dated: June 30, 2006

Received: July 3, 2006

Dear Ms. Bickoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

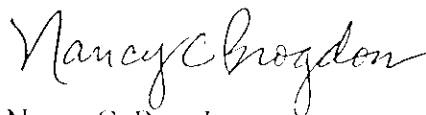
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): ~~To Be Determined~~ K061877

Device Name: Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System

Indications For Use:

The Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

R. C. Phillips Concurrency of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K061877